UK DECLARATION OF CONFORMITY (*Self Certification*)
CLASS 1 REUSABLE SURGICAL INSTRUMENTS

Name & Address of Manufacturer	Bolton Surgical Limited 16 Churchill Way, Chapeltown, Sheffield, South Yorkshire, UK, S35 2PY Tel: (00 44) 114 2404400 Web: www.boltons.co.uk
Responsibility:	This declaration of conformity is issued under the sole responsibility of the manufacturer.
Unique Device Identification:	Applicable Bolton Surgical Product Code, Global Trade Identification Numbers (GTIN's) and relevant Nomenclature codes are assigned to all products.
Intended Use:	Bolton Surgical reusable surgical instruments are intended for use by appropriately qualified surgical practitioners to perform specific functions such as cutting, scraping, grasping, dissecting, probing, retracting, draining, suturing, or ligating and other similar procedures, as indicated on the Instructions For Use supplied with the product or available at www.boltons.co.uk .
Classification Route:	These devices are all intended for transient use, are reusable, and include surgically invasive, invasive and non-invasive medical devices, supplied non-sterile. The classification is determined in accordance with UK Medical Device Regulations 2002 (UK MDR S.I. 2002/618)
Assessment Route:	In accordance with UK Medical Device Regulations 2002 (UK MDR S.I. 2002/618), the reusable surgical instruments covered by this Declaration of Conformity have been designated as **Class I** and as such are self-certified by Bolton Surgical Ltd and UKCA marked accordingly.
Notified Body Name & Address:	Not Applicable. Class I devices do not require Approved/Notified Body Intervention

Bolton Surgical Limited declares that the Class 1 reusable Surgical Instruments listed and coded within the Company catalogue and website are manufactured in accordance with the requirements of our Quality Management System certified to ISO13485:2016 (cert no. MD500657) and UK Medical Device Regulations 2002 (UK MDR S.I. 2002/618).
Bolton Surgical reusable surgical instruments are manufactured from materials suitable for sterilisation and, as relevant and applicable, in accordance with the requirements of one or more of the common/harmonised standards and guidance documents listed below:

Standard:	***Details:***
EN ISO 13485	Medical devices -- Quality management systems -- Requirements for regulatory purposes.
UK MDR 2002	UK Medical Device Regulations
EN ISO 7153-1	Surgical Instruments. Materials. Metals
BS 5194:Part 2	Specification for instruments with pivot joints (excluding cutting instruments)
BS 5194:Part 3	Specification for Dissecting Forceps
BS 5194:Part 4	Specification for scissors, shears, and other jointed cutting instruments
ISO 7151	Surgical instruments – non-cutting, articulated instruments – general requirements & test methods
ISO 7741	Scissors and shears - General requirements and test methods
ISO 9714-1	Orthopaedic drilling instruments Part 1: Drill bits, taps and countersink cutters
ISO 6508-1	Specifies the method for Rockwell and Rockwell superficial hardness tests for metallic materials
EN ISO 14971	Medical Devices – Application of risk management to medical devices
DIN 58299	Serrations for surgical instruments; profile angles, groove distances
DIN 58300	Joints for surgical instruments
DIN 96298-3	Medical Instruments - Tests
BS EN ISO 17664	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
BS EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO 13402	Surgical and Dental hand instruments. Determination of risistance against autoclaving, corrosion & thermal exposure.
HTM 01-01	Health Technical Memorandum (HTM01-01) - Management and decontamination of surgical instruments (medical devices) used in acute care.
BS EN ISO 17665	Sterilization of health care products — Moist heat —Requirements for the development, validation and routine control of a sterilization process for medical devices

Signed, for and on behalf of Bolton Surgical Ltd:	***Lyndsey J Bolton, - Managing Director***	Date: 08/01/2025

The above-named signatory is the natural and legal person with responsibility for the design, manufacture, packaging, and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on their behalf by a third party.